News Release

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Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma announces closure to further patient accrual on its CO.23 study: a phase III global colorectal carcinoma monotherapy trial

Osaka, Japan, May 23, 2014 – Dainippon Sumitomo Pharma Co., Ltd. (Head office: Osaka, Japan; President: Masayo Tada) ("DSP") announced today closure to further accrual of patients on its CO.23 study. The protocol-defined first interim analysis of the initial 97 patients enrolled into its CO.23 study has been completed. DSMC recommended that further enrollment of new patients be stopped and all study drug be discontinued because while there is no safety concern, the futility analysis, based on disease control rate, met protocol defined criteria for stopping. The approximate 280 patients who have been enrolled into this study will be unblinded and be followed for overall survival, the primary endpoint of the CO.23 study.

CO. 23 study is a randomized, double-blind, placebo-controlled monotherapy study of BBI608 in patients with advanced colorectal carcinoma who have failed all available therapies. Several other trials raging from phase III to phase I are currently being conducted for BBI608 in patient with various tumor types in various combination regimens. DSP will continue all these ongoing clinical trials and proceed with the development of BBI608 with the aim to obtain its market authorization as early as possible.

We are currently examining the effects that this matter will have on the consolidated business performance of DSP and will promptly make an announcement if we find that there is a need to make further disclosures.

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